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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,783	05/02/2002	John C. Herr	00415-03	8483

34444 7590 12/16/2003

UNIVERSITY OF VIRGINIA PATENT FOUNDATION
1224 WEST MAIN STREET, SUITE 1-110
CHARLOTTESVILLE, VA 22903

EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/031,783	HERR et al.
Examiner	**Art Unit**
James L. Grun, Ph.D.	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-3, 5-7, 9-19, and 33-36* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3, 5-7, 9-19, and 33-36* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 5, 6, 13, and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant suggests the conjugation of the recombinant antibody to toxins, microbicides, or virucides, but the specification provides no description or guidance for how one makes use of a sperm-specific antibody for delivery of toxins, microbicides, or virucides. No condition is taught as amenable to treatment with such a conjugate, one would not readily know for what condition such a conjugate would predictably function in the absence of further description and

guidance from applicant, and, even if such a condition were identified, applicant's specification provides no description or guidance for appropriate delivery, dosages, or any other properties needed for use of such conjugates. There is no nexus between any in vitro method and any in vivo function of any agent taught in applicant's specification. The in vivo success of any therapeutic composition is dependent not only upon a particular mode of action but also upon adequate concentrations of drug reaching the desired site of activity. There are many other pharmacokinetic properties of drugs such as half-life, deactivation, binding to plasma proteins, rapid excretion, etc. that would need to be determined and set forth to establish any in vivo function, particularly for a currently unspecified condition. Extensive further experimentation would be required. Such experimentation is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-7, and 9-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and claims dependent thereupon, "the S19 monoclonal antibody" lacks antecedent basis and is vague in the absence of recitation of deposit accession number.

In claim 9, it is not clear for what the composition is active.

In claim 18, "the presence" lacks antecedent basis. The claim is confusing because the preamble recites detecting sperm but the body of the claims do not recite a step relating washing the solid support to detecting sperm.

In claim 19, "the S19 monoclonal antibody" lacks antecedent basis and is vague in the absence of recitation of deposit accession number.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-3, 7, 9-12, 15-19, and 33-36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Herr et al. (US 5,830,472) in view of Owens et al (J. Immunol. Meth. 168: 149, 1994).

Herr et al. (US 5,830,472) teach the S19 monoclonal antibody, produced by the hybridoma deposited as ATCC HB12144, and the use of the antibody as a spermicide or diagnostic. The

reference teaches that, using the sequence of the antibody, conventional techniques can be employed to provide recombinant antibodies (see e.g. column 9, lines 3-7). The reference discloses methods for the isolation and sequencing of the variable regions of the heavy and light chains of the antibody from the hybridoma cell line and reports what were determined to be the genomic sequences of the cloned chains. Although the instant specification teaches that the light chain sequence disclosed in the reference contained errors, the sequences of the antibody chains produced by the deposited hybridoma and clonable from the teachings of the reference are a property thereof possessed and readily obtainable by one in possession of the deposited cell line. In contrast to the invention as instantly claimed, the reference does not specifically teach single chain Fv antibody fragments.

Owens et al (J. Immunol. Meth. 168: 149, 1994) teach conventional techniques for genetic engineering of monoclonal antibodies for a variety of benefits, including to provide a more stable, higher-yield, and/or lower cost production means for the monoclonal antibodies than hybridomas. For example the production of single chain Fv fragments wherein the variable regions of the heavy and light chains are linked together in a single polypeptide with a linker such as oligomers of (Gly_4Ser) (see e.g. pages 155-156).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have recombinantly engineered the S19 monoclonal antibody of Herr et al. using the conventional techniques as taught by Owens et al. motivated by the direct suggestion in Herr et al. to do so and by the benefits taught by Owens et al. to provide a more stable, higher-yield, and/or

lower cost production means for the monoclonal antibodies than hybridomas. It would have been obvious to have optimized the length of the conventional oligomeric linker.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Herr et al. (US 5,605,803) is incorporated by reference in Herr et al. (US 5,830,472) for methodological details for the use of the antibody as a diagnostic.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.

James L. Grun, Ph.D.
December 13, 2003

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641